

SEP - 2 1999



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Washington, D.C. 20231

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Washington Harbour, Suite 500
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Washington DC 20007-5109

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,362,567

#19

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,362,567, which claims the human biologic product TISSEEL VH Kit, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be **two years**.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of two years.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of November 25, 1998 (63 Fed. Reg. 65211). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,203) + 3,862 \\ &= 4,464 \text{ days}\end{aligned}$$

Since the regulatory review period began June 20, 1984, after the patent issue date (December 7, 1982), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The two year limitation of 35 U.S.C. § 156(g)(6)(C) applies in the present situation because the patent was issued and an action described in 35 U.S.C. § 156(g)(6)(B) was taken (e.g., a request for an exemption) before the date of enactment of 35 U.S.C. § 156 (September 24, 1984). Specifically, the submission of an investigational new drug (IND) application is a request for an exemption under subsection 505(i) of the Federal Food, Drug and Cosmetic Act. (See 21 U.S.C. § 355(i) and 21 C.F.R. Part 312.) Since the exemption became effective on June 20, 1984, as claimed by applicant, under 35 U.S.C. § 156(g)(6)(C), the period of extension will be for two years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.	:	4,362,567
Granted	:	December 7, 1982
Original Expiration Date	:	February 4, 2000
Applicant	:	Otto Schwarz, et al.
Owner of Record	:	Immuno Aktiengesellschaft für chemisch-medizinische Produkte
Title	:	Tissue Adhesive
Classification	:	106/157
Product Trade Name	:	TISSEEL VH KIT
Term Extended	:	Two years
Expiration Date of Extension	:	February 4, 2002

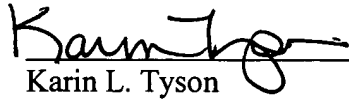
Any correspondence from applicant with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Special Program Law Office

By hand: Crystal Plaza Four, Suite 3C23
2201 South Clark Place
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Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.



Karin L. Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read
Acting Director Regulatory Policy Staff, CDER
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RE: TISSEEL VH KIT
FDA Docket No.: 98E-0791